

REMARKS/ARGUMENTS

Claims 1-3, 5-7, 10, 12, 14, and 16-27 have been examined. Dependent claims 8, 11, and 13 stand withdrawn as being drawn to a non-elected species. Currently, claim 1 is generic. Re-examination and reconsideration of the pending claims 1-3, 5-8, 10-14, and 16-27 are respectfully requested.

Claims 1-3, 5-7, 10, 12, 14, 16-23, and 27 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 4,681,560 issued to Schulte et al. in view of U.S. Patent No. 4,569,675 issued to Prosl et al. Claims 24-26 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Schulte et al. in view of U.S. Patent No. 6,162,238 issued to Kaplan et al. Such rejections are traversed.

Independent claim 1 is directed towards an implantable port comprising a port body having a flow passage therethrough and a pressure-responsive valve. The flow passage has an upstream end and a downstream end, wherein at least a portion of the upstream end is adapted to sealingly engage an access tube which is inserted into said upstream end. In particular, claim 1 recites that the pressure-responsive valve element is positioned in the flow passage and integrally formed with the port body downstream from the upstream portion so that an access tube can be fully inserted into said upstream portion without engaging the valve component, wherein the valve component is closed in the absence of a differential pressure above a threshold level.

As the Examiner certainly knows and appreciates, *prima facie* obviousness requires that the prior art references, alone or in combination, teach or suggest **all** the claim limitations. M.P.E.P. § 2143.03; *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974). In the instant case, the claimed integral pressure-responsive valve element within the port body of claim 1 has not been reasonably disclosed or suggested by any of the cited art references. Secondly, no suggestion or motivation, either in the cited references or in the knowledge generally available to one of ordinary skill in the art, has been cited by the Examiner for the proposed combination or modification of the reference teachings so as to produce the claimed invention. M.P.E.P. § 2143.01; *In re Fine*, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

As the Examiner has already acknowledged, the Schulte et al. patent fails to disclose "the pressure-responsive valve integrally formed to the port body". Office Action, pages 2 and 3. The Schulte et al. reference, with reference to Figs. 1 and 7, instead describes an injection site apparatus (28) having an outlet (58), wherein a separate flexible tubing structure (26) is connected to the injection site apparatus (28) via outlet (58) and to a reservoir (12). In particular, the flexible tubing has an inlet end (56) which includes a one way valve (60) situated therein (26) to prevent reverse flow of medication from the reservoir (12). See col. 7, lines 25-32. Hence, this reference fails to teach or suggest a valve as an element of the port, much less a valve integrally formed within the port. Similarly, the Prosl et al. reference fails to even remotely suggest the use of a pressure-responsive valve structure in its transcutaneous infusion system. Applicants request, if the present rejection is maintained, that the Examiner show or explain where the cited references, alone or in combination, teach or suggest an integral pressure-responsive valve element within the port body as presently claimed.

Secondly, based on the Schulte et al. or Prosl et al. references, one of ordinary skill in the art would not have been reasonably motivated to modify any of these reference teachings to produce Applicants' claimed device. The Examiner asserts that "it would have been obvious to one of ordinary skill in the art to integrally mount the pressure-responsive valve of Schulte in the port body thereof...." Office Action, pages 2-3. Applicants point out that the Examiner bears the initial burden of factually establishing and supporting any *prima facie* conclusion of obviousness. *In re Rinehart*, 189 U.S.P.Q. 143 (CCPA 1976); M.P.E.P. § 2142. If the Examiner does not produce a *prima facie* case, the Applicant is under **no** obligation to submit evidence of nonobviousness. *Id.* In the instant case, the Examiner has not pointed to any evidence in the reference teachings themselves which teaches or suggest their modification. See *In re Zurko*, 59 U.S.P.Q.2d 1693 (Fed Cir. 2001) ([I]n a determination of patentability the Board cannot simply reach a conclusion based on its own understanding or experience - or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings). Hindsight reconstruction is not permissible.

Moreover, even assuming *arguendo* that the Schulte reference et al. could be modified, it would at best result in the valve (60) being integrated into the separate flexible tubing structure (26) which still falls far short of the present invention. Hence, absent any cited teaching or suggestion for an implantable port comprising a pressure-responsive valve element integrally formed with the port body as recited in claim 1, claim 1 (and dependent claims 2, 3, 5-8, 10-14, 16 and 24-27) are now in condition for allowance.

Independent claim 17 recites a method for delivering a substance to a subcutaneous target site. The method similarly comprises, in part, percutaneously introducing an access tube to an implanted port having a flow passageway with an upstream end, a downstream end, and a valve element in the flow passageway and integrally formed with the port, wherein the access tube is introduced to seat in the passage but does not engage the valve element. Hence, claim 17 (and dependent claims 18-23) are allowable for many of the reasons given above regarding claim 1.

Dependent claims 24-26 depend on claim 1 and as such should be allowable for many of the reasons given above regarding claim 1. Further, it should be noted that the cited art rejection is moot as the Kaplan et al. reference is not prior art to the present application. The Kaplan et al. reference has an effective filing date of February 24, 1999. The present application is a continuation-in-part of and claims priority from Application No. 09/239,411 filed on January 28, 1999. Applicants believe that claims 24-26 are fully supported under 35 U.S.C. § 112 in the '411 parent application. Hence, the present application has an effective filing date of January 28, 1999 and as such the Kaplan et al. reference does not appear to be prior art to the present application. Hence, for this additional reason Applicants respectfully request that the § 103(a) rejection be withdrawn and claims 24-26 be allowed.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Appl. No. 09/595,167
Amdt. dated [insert date]
Reply to Office Action of July 9, 2003

PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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